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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/514,070	02/26/2000	Merrill A Biel	22272-14	8621

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EXAMINER

SHAY, DAVID M

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 02/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/514,070

Applicant(s)

Baill

Examiner

d. shay

Group Art Unit

3739

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on January 9, 2001
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-102 is/are pending in the application.
- ☐ Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-102 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No. 2
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

Application/Control Number: 09/514,070
Art Unit: 3739

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 13, 16-18, 22-25, 38-46, 61-65, 73-78, 80, 84, 85, and 92-94 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 is indefinite because it does not limit the cell population to which the method is to be applied. In claims 16-18, 23-25, 38-46, 61-65, 73-78, 84, and 85 it is unclear what, further manipulation is intended to be encompassed thereby. In claims 22 it is unclear what further structure is intended to be claimed. Claim 92 is indefinite because it is unclear how the compositions are "adapted to be disposed in proximity to the ... cell site" when there is nothing inherent therein that would prevent such placement thereof also "the pathogen cell site" lacks positive antecedent basis. In claim 80 "the step of disposing... human body" lacks positive antecedent basis

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Application/Control Number: 09/514,070
 Art Unit: 3739

4. Claims 1, 3, 7-13, 15-19, 22-28, 38-46, 49, 52, 60, 62, 63, 67-69, 81-89, 92, 93, 95, 97, and 98 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by

Lyons.

5. Claims 1, ^{4-12,} ~~12~~ 14, 15, 18, 19, 22-28, ^{34, 37-46} ~~34-37, 46~~ 49, 50, 60, 61, 63, 67-71, 81-92, ^{dm} 95, 96, and 98 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by

Williams et al.

6. Claims 1-3, 6, 8, 10-13, 15, 18, 26, 30, 32, 37, 39, 44, 45, 48, 49, 51, 52, 80-83, 86, 87, 92, 95 and 97 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Nitzan et al.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claim 9, 20, 21, 92, 94, 95 and 99-102 are rejected under 35 U.S.C. 103(a) as

being unpatentable over Lyons in combination with Nitzan et al.

Lyons teaches a treatment arrangement such as claimed except for the particular surfactant, the particular sensitizer and the plurality of sensitizers. Nitzan et al teach a composition such as claimed except for the use of SDS, an amphoteric surfactant, ^e methylene blue, and a mixture of photosensitizers. It would have been obvious to the artisan of ordinary skill to employ polymyxin B or SDS and the claimed concentrations thereof in the solution of Lyons since these are notorious surfactants in the art, official notice of which is hereby taken, to employ methylene blue, since this is

notorious as a photosensitizer in the art, official notice of which is hereby taken and to employ a mixture of photosensitizers, since this would allow treatment of multiple conditions simultaneously and provides no unexpected result, thus producing a kit and solution such as claimed

9. Claims 10, 16, 17, 26, 29-33, 35, 36, 47, 49, ^{53, 60}~~52-59~~, 64-66, and 72-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lyons in combination with Nitzan et al.

The teachings of Lyons and Nitzan et al., ^{and} on the motivations for combination and ⁱⁿ modification thereof, and the official notice are essentially those already interated in the rejection of claims 9, 20, 21, 92, 94, 95, and 99-102 above. Additionally performing the methods as part of a sterilization procedure, in conjunction with an infected wound, or ^{with gram} positive bacteria would have been obvious, since it is effective against drug resistant bacteria; would be useful in the case of, for example an ulcerated bowel tumor; and in the presence of gram positive infectious agents, respectively, thus producing a method such as claimed.

10. Claims 54, 55, and 57-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swartz et al in combination with Asculai et al. Swartz et al teach a method such as claimed except for the use of a surfactant. Asculai et al teach the use of surfactants to inactivate viruses. It would have been obvious to the artisan of ordinary skill to employ a surfactant in the method of Swartz et al since this would further inactivate the virus and would help adjust the properties of the gel official

Application/Control Number: 09/514,070
 Art Unit: 3739

notice of which is hereby taken, to employ SDS, since this is a notorious non ionic surfactant in the art, official notice of which is hereby taken and to employ a concentration in the claimed range, since this provides no unexpected result, thus producing a method such as claimed.

11. Claim 56 is rejected under 35 U.S.C. 103(a) as being unpatentable over Swartz et al in combination with Asculai et al as applied to claim 55 above, and further in view of Nitzan et al. Nitzan et al teach the irradiation dosage and dosage rates claimed. It would have been obvious to the artisan of ordinary skill to employ the dosage and dosage rates taught by Nitzan et al, since these are appropriate for causing DNA alterations and thus inactivation, as taught by Nitzan et al, and since these are determinable by routine experimentation and provides no unexpected results, thus producing a method such as claimed.

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 1-102 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No.

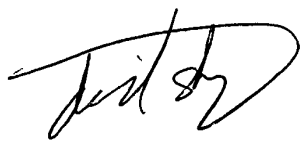
Application/Control Number: 09/514,070
Art Unit:3739

6,251,127 in view of Rothstein. Rothstein teaches the equivalence of polymyxin B and SDS as surfactants. It would have been obvious to the artisan of ordinary skill to employ SDS, since this is equivalent to polymyxin B, as taught by Rothstein, and to employ the mixtures in the various claimed methods, since methylene blue is notorious as a photosensitizer useful in such methods, official notice of which is hereby taken, and to employ the various types of surfactants, since these are equivalents in the art, thus producing a method, kit and solution, such as claimed.

Any inquiry concerning this communication should be directed to David Shay at telephone number (703) 308-2215.

David Shay:bhw

February 16, 2002



DAVID M. SHAY
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GROUP 330